

# United States Patent and Trademark Office

DEPARTMENT OF COMMERCE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO.           | FILING DATE      | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|------------------|----------------------|---------------------|------------------|
| 10/520,659                | 01/10/2006       | Osami Habuchi        | Q85706 5610         |                  |
| 65565<br>SUGHRUE-26       | 7590 05/30/2007  |                      | EXAMINER            |                  |
| 2100 PENNSYLVANIA AVE. NW |                  |                      | BLAND, LAYLA D      |                  |
| WASHINGTO                 | N, DC 20037-3213 |                      | ART UNIT            | PAPER NUMBER     |
|                           |                  |                      | 1609                |                  |
|                           |                  |                      |                     |                  |
|                           |                  |                      | MAIL DATE           | DELIVERY MODE    |
|                           |                  |                      | 05/30/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|   | Application No.   | Applicant(s)   |  |  |  |  |
|---|---|--|--|--|--|--|
|   | 10/520,659  | HABUCHI ET AL.   |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit   |  |  |  |  |
|   | Layla Bland   | 1609   |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply  | ears on the cover sheet with the c  | orrespondence address  |  |  |  |  |
|   | VIC SET TO EVOIDE AMONTH  | e) OB TUIDTY (20) DAVE   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING Do  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period of  - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |
| Status  |   |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 11 M   | ay 2007.  |  |  |  |  |  |
| ,   | <del>-</del>  |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |   |  |  |  |  |  |
| closed in accordance with the practice under E  | x parte Quayle, 1935 C.D. 11, 4:  | 53 O.G. 213.   |  |  |  |  |
| Disposition of Claims   |   |  |  |  |  |  |
| 4) Claim(s) 1-12 is/are pending in the application.   |   |  |  |  |  |  |
| 4a) Of the above claim(s) <u>7-12</u> is/are withdrawn from consideration.  |   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |   |  |  |  |  |  |
| ·   | 6)⊠ Claim(s) <u>1-6</u> is/are rejected.  |  |  |  |  |  |
| 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/o  | r election requirement  |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/o  | r election requirement.   |  |  |  |  |  |
| Application Papers  |   |  |  |  |  |  |
| 9) The specification is objected to by the Examine  |   |  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |   |  |  |  |  |  |
| Applicant may not request that any objection to the   | ·   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex   |   |  |  |  |  |  |
| · ·   |   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   | ) (-1) (f)   |  |  |  |  |
| 12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |   |  |  |  |  |  |
| a)⊠ All b)□ Some * c)□ None of: 1.□ Certified copies of the priority documents have been received.  |   |  |  |  |  |  |
| Certified copies of the priority documents have been received in Application No   |   |  |  |  |  |  |
| 3.⊠ Copies of the certified copies of the priority documents have been received in this National Stage  |   |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |   |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |   |  |  |  |  |  |
|   |   | •  |  |  |  |  |
|   |   |  |  |  |  |  |
| Attachment(s)   |   |  |  |  |  |  |
| Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 4) 🔲 Interview Summary<br>Paper No(s)/Mail Da   |  |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 01/10/2005, 04/07/2006.   | 5) Notice of Informal F 6) Other:   |  |  |  |  |  |

Application/Control Number: 10/520,659

Art Unit: 1609

#### **DETAILED ACTION**

Applicant's election without traverse of Group I, claims 1-6, on May 11, 2007 is acknowledged. Claims 7-12 are withdrawn from consideration as being drawn to non-elected invention. Claims 1-6 are examined on the merits herein.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 recite the limitation, "substituted or unsubstituted aryl" (or alkyl, alkenyl, alkynyl, acyl, and aralkyl, in the case of claim 1). The specification [page 7] gives a list of which groups these moieties can be substituted with, ending with "or the like." The claims are indefinite because phrase "or the like" leaves the definition of "substituted" open-ended, including elements which are not actually disclosed.

Claims 5 and 6 recite the limitation "a sulfotransferase inhibitor which comprises the galactosamine derivative according to claim 1." "Comprises" is open language, allowing for the inclusion of other elements besides the derivative of claim 1. It is unclear whether the claims are intended to be compound claims or composition claims. The claims have been interpreted as compound claims for the purposes of examination.

Application/Control Number: 10/520,659

Art Unit: 1609

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Habuchi, et al. (The Journal of Biological Chemistry 1985, Vol. 260, No. 24, 13102-13108, PTO-1449 submitted January 10, 2005).

Habuchi, et al. teach pNP-GalNAc-6-SO<sub>4</sub> [page 13106, column 2, line 43]. In this case,  $R_5 = SO_3$ ,  $R_1$  and  $R_2$  are both represented by H,  $R_3$  is an acetyl group, X is O, and  $R_4$  is 4-nitrophenyl (a substituted aryl group). The limitations of claims 5 and 6, which are drawn to a sulfotransferase inhibitor which comprises the derivative of claim 1 and inhibits activity of a sulfotransferase having activity of transferring a sulfate group to a hydroxyl group bound to the 6-position carbon atom on the 4-sulfated galactosamine residue in the basic backbone of chondroitin suflate, are inherent properties of the derivative of claim 1 and thus are also met by this compound.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Dahlgren, et al. (WO 97/00879, January 9, 1997, PTO-1449 submitted January 10, 2005).

Dahlgren, et al. teach compounds of the following formula:

Application/Control Number: 10/520,659

Art Unit: 1609

$$x^{4}$$
 $x^{1}$ 
 $x^{2}$ 
 $x^{3}$ 
 $x^{2}$ 
 $x^{2}$ 
 $x^{3}$ 
 $x^{2}$ 
 $x^{2}$ 
 $x^{3}$ 
 $x^{2}$ 

wherein X³, X⁴ and X⁶ can all be OH or SO₄, R² can be OH, SO₄ or substituted amine including NHAc, and R¹ can be hydrogen, alkyl, benzyl, amino acid, nucleotide or polypeptide. When R² is NHAc and R¹ is benzyl: The limitations of claim 1 are met when any or all of X³, X⁴ and X⁶ are SO₄; the limitations of claim 2 are met when X⁶ is SO₄ and X³ and X⁴ are both OH; the limitations of claim 3 are met when X⁴ is SO₄ and X⁶ and X³ are both OH; the limitations of claim 4 are met when X³ is SO₄ and X⁶ are both OH. The limitations of claims 5 and 6, which are drawn to a sulfotransferase inhibitor which comprises the derivative of claim 1 and inhibits activity of a sulfotransferase having activity of transferring a sulfate group to a hydroxyl group bound to the 6-position carbon atom on the 4-sulfated galactosamine residue in the basic backbone of chondroitin suflate, are inherent properties of the derivative of claim 1 and thus are also met by this compound.

### Conclusion

No claims are allowed in this application.

Application/Control Number: 10/520,659 Page 5

Art Unit: 1609

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ldb

SUPERVISORY PATENT EXAMINER